UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: TASIGNA (NILOTINIB)
PRODUCTS LIABILITY LITIGATION

Case No. 6:21-md-3006-RBD-DAB
(MDL No. 3006)

This document relates to
Member Case No. 6:21-cv-1327.

ORDER

Before the Court are:

1. Defendant Novartis Pharmaceuticals Corporation's Motion for Certification for Interlocutory Appeal (Doc. 92 ("Motion")); and
2. Plaintiff's Memorandum in Opposition to Defendant's Motion for Certification for Interlocutory Appeal (Doc. 93).

Defendant's Motion is due to be denied.

In this drug MDL member case, Defendant previously moved for judgment on the pleadings, arguing that Plaintiff's claims are preempted because no newly acquired information was discovered that would have allowed Defendant to change the label without FDA approval. (Doc. 87.) The Court denied that motion, holding that Plaintiff need not plead around the affirmative defense of preemption in her Complaint and the Complaint sufficiently alleged newly acquired information requiring a label change. (Doc. 91, pp. 2–4; Case No. 6:21-md-3006, Doc. 50, pp. 13:1–14:10.) Defendant now moves this Court to certify the issue to

the U.S. Court of Appeals for the Eleventh Circuit for interlocutory review under 28 U.S.C. § 1292(b). (Doc. 92.)

"Because permitting piecemeal appeals is bad policy, permitting liberal use of § 1292(b) interlocutory appeals is bad policy." *McFarlin v. Conseco Servs., LLC*, 381 F.3d 1251, 1259 (11th Cir. 2004); *see also Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1276 (11th Cir. 2000) ("[I]nterlocutory appeals are inherently disruptive, time-consuming, and expensive, and consequently are generally disfavored." (cleaned up)). A movant seeking interlocutory review bears the burden of showing that the case is a "rare exception" to the piecemeal appeal rule and that the issue "involves a controlling question of law upon which there is . . . a substantial ground for difference of opinion, and . . . immediate appeal from the order may materially advance the ultimate termination of the litigation." *Cont'l 332 Fund, LLC v. Albertelli*, No. 2:17-cv-41, 2018 WL 3656472, at *2 (M.D. Fla. Aug. 2, 2018) (cleaned up).

Here, Defendant meets none of the elements required for the Court to consider certification. Defendant argues that the Court should not have accepted as true the factual allegations in Plaintiff's Complaint indicating that Defendant had newly acquired information—asserting instead that this is a legal conclusion. (Doc. 92.) But this is not a pure question of law for the Eleventh Circuit's consideration; it is a question of applying "settled law to facts," which is not an

appropriate subject of interlocutory review. *See Mamani v. Berzain*, 825 F.3d 1304, 1313 (11th Cir. 2016); *Albertelli*, 2018 WL 3656472, at *2. Of course, there can be no grounds for a difference of opinion on the black-letter law that the Court must accept factual allegations as true at this stage. *See United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1269 (11th Cir. 2009); *White v. State Nat'l Ins. Co.*, No. 8:12-cv-2828, 2013 WL 12156318, at *1 (M.D. Fla. Apr. 12, 2013). That is exactly what the Court did, citing to the specific *factual* allegations in the Complaint supporting the conclusion that Defendant had newly acquired information.[1] (*See* Doc. 91, p. 4 (citing Doc. 1, ¶ 38 ("This newly acquired information came in the form of (1) multiple reports from their clinical investigators, (2) multiple medical studies and reports, (3) data from a phase 3 randomized clinical trial, and (4) adverse event information gathered in a Novartis global safety database.")).) Nor can there be grounds for a difference of opinion on whether Defendant, not Plaintiff, bears the burden of proving its own affirmative defense—a burden that is particularly "demanding" when the defense is preemption. *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *see also La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) ("[P]laintiffs are not required to negate an affirmative defense in their complaint." (cleaned

[1] Defendant's cited cases are inapposite because in those cases—unlike here—the plaintiffs did not provide any plausible factual predicate. (Doc. 92, p. 12); *cf., e.g., Goodell v. Bayer Healthcare Pharms. Inc.*, No. 18-CV-10694, 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019) ("[T]he complaint does not cite *any* newly acquired information that arose after the FDA's approval." (emphasis added)).

up)). Finally, certifying this issue would stall rather than advance the litigation, as Plaintiff would likely be permitted to amend to cure any pleading deficiencies, and the parties are barreling quickly toward the discovery deadline. *See Albertelli*, 2018 WL 3656472, at *4 ("[I]t strains credulity to argue an interlocutory appeal of this matter would expedite litigation."). With none of the elements met, Defendant has not carried its burden of demonstrating that this issue is appropriate for interlocutory review.

This case is not the "rare exception"—it is the rule. Defendants are often unhappy with courts' findings that complaints are sufficiently pled. That unhappiness does not warrant putting the brakes on this litigation just as it is starting to pick up steam.[2]

Accordingly, it is **ORDERED AND ADJUDGED** that Defendant's Motion (Doc. 92) is **DENIED**.

DONE AND ORDERED in Chambers in Orlando, Florida, on January 4, 2022.

[2] (*See* Case No. 6:21-md-3006, Doc. 50, p. 14:11–16 ("[P]art of the reason I wanted to get [the motion for judgment on the pleadings] out of the way is I don't want that to be an impediment to moving forward with respect to discovery. And I appreciate the fact that Novartis disagrees with my determination of the adequacy of the Complaint, and that is not unexpected.").)

ROY B. DALTON JR.
United States District Judge